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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/074,575	02/11/2002	Joseph Rubinfeld	12636-264	6758

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EXAMINER

KAM, CHIH MIN

ART UNIT PAPER NUMBER

1653

DATE MAILED: 06/17/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

<b>Office Action Summary</b>	<b>Application No.</b> 10/074,575	<b>Applicant(s)</b> RUBINFELD, JOSEPH	
	<b>Examiner</b> Chih-Min Kam	<b>Art Unit</b> 1653	

**-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --**

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☐ Responsive to communication(s) filed on \_\_\_\_.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 19-23 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 19-23 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \*    c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- |                                                                                                                                             |                                                                                         |
|---------------------------------------------------------------------------------------------------------------------------------------------|-----------------------------------------------------------------------------------------|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)                                                                 | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. ____. |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                                                        | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)             |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)<br>Paper No(s)/Mail Date <u>6/4/02</u> . | 6) <input type="checkbox"/> Other: ____.                                                |

### DETAILED ACTION

1. In the preliminary amendment filed February 11, 2002, claims 1-18 have been cancelled, and new claims 19-23 have been added, therefore claims 19-23 are examined.

#### *Abstract*

2. In the preliminary amendment filed February 11, 2002, a new abstract has been submitted, however, the abstract of the disclosure does not commence on a separate sheet in accordance with 37 CFR 1.52(b)(4). A new abstract of the disclosure is required and must be presented on a separate sheet, apart from any other text.

#### *Claim Objections*

3. Claims 19 and 20 are objected to because a misspelled word "5-fluoruracil".  
Use of "5-fluorouracil" is suggested.

#### *Claim Rejections-Obviousness Type Double Patenting*

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

4. Claims 19-23 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-16, 18-21, 23 and 25 of co-pending application 10/081,974 (US 2003/0158148, where claims 17, 22, 24 and

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26-53 have been cancelled). Although the conflicting claims are not identical, they are not patentably distinct from each other because claims 19-23 in the instant application disclose a method for treating a patient having a disease associated with undesirable or uncontrolled cell proliferation, the method comprising delivering a therapeutically effective amount of 9-nitro-20(S)-camptothecin and delivering a therapeutically effective amount of 5-fluorouracil to the patient. This is obvious in view of claims 1-16, 18-21, 23 and 25 of the co-pending application which disclose a method for treating cancer in a cancer patient comprising administering to the patient a water-insoluble 20(S)-camptothecin for a period of time during which 5-fluorouracil is not administered; and administering to the patient 5-fluorouracil, wherein the period of time is at least 1 day, and wherein the water-insoluble 20(S)-camptothecin is 9-nitro-20(S)-camptothecin or 9-amino-20(S)-camptothecin. Since both sets of claims encompass a method for treating a disease associated with undesirable or uncontrolled cell proliferation such as cancer, the method comprising administering to the patient 9-nitro-20(S)-camptothecin; and administering to the patient 5-fluorouracil. Therefore, claims 19-23 in instant application and claims 1-16, 18-21, 23 and 25 of the co-pending application are obvious variations of treating a patient having a disease associated with undesirable or uncontrolled cell proliferation, the method comprising delivering a therapeutically effective amount of 9-nitro-20(S)-camptothecin and delivering a therapeutically effective amount of 5-fluorouracil to the patient.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

***Claim Rejections - 35 USC § 112***

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

5. Claims 19-23 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.
6. Claims 19-23 are indefinite because the claims lack an essential step in the method of treating a patient having a disease associated with undesirable or uncontrolled cell proliferation. The missing step is the outcome of the treatment, it is not clear what the therapeutically effective amount of 9-nitro-20(S)-camptothecin and the therapeutically effective amount of 5-fluoruracil would do in the combination therapy? Claims 19-23 are also indefinite as to how the two active agents are delivered to the patient, e.g., are the two agents administered together, or separately, or, simultaneously or subsequently? Claims 19-23 are also indefinite because of the use of the term “a 9-nitro-20(S)-camptothecin” or “a 5-fluoruracil”, it is not clear how a specific compound such as 9-nitro-20(S)-camptothecin or 5-fluoruracil, which has a defined structure, is referred as “a 9-nitro-20(S)-camptothecin” or “a 5-fluoruracil”, which indicates more than one compound of 9-nitro-20(S)-camptothecin or 5-fluoruracil. Claims 20-23 are included in the rejection because they are dependent on a rejected claim and do not correct the deficiency of the claim from which they depend.
7. Claim 20 is indefinite because the claim does not further limit the scope of claim 19. Claim 19 recites the method comprising delivering 9-nitro-20(S)-camptothecin to the

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patient, and delivering 5-fluoruracil to the patient; and claim 20 recites the two active agents are delivered in combination but it does not indicate how the two agents are delivered in regard to the formulation of the agents and the time frame for delivering, thus claim 19 does not further limit the scope of claim 19.

***Conclusion***

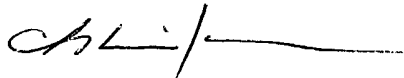
8. No claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Chih-Min Kam whose telephone number is (571) 272-0948. The examiner can normally be reached on 8.00-4:30, Mon-Fri.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christopher Low can be reached on (571) 272-0951. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 872-9306 for regular communications and (703) 308-4227 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.

Chih-Min Kam, Ph. D.  
Patent Examiner



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June 10, 2004